

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gerianne Tringali DiPiano, Peter Kevin Mays, and John Ziemniak

Serial No.: 10/751,056

Art Unit: 1617

Filed: January 2, 2004

Examiner: Jennifer M. Kim

For: *PHARMACEUTICAL PREPARATIONS FOR TREATMENTS OF DISEASES
AND DISORDERS OF THE BREAST*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. § 1.56 and 37 C.F.R. § 1.97,

Applicants submit a Supplemental Information Disclosure Statement, including one (1) page of Form PTO-1449, and copies of the four (4) documents cited therein.

This Supplemental Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(c) after a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-3129.

Certification Under 37 C.F.R. § 1.97 (e)(1)

Each item of information contained in this Supplemental Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Supplemental Information Disclosure Statement.

Publications

COLACURCI, et al., "Effects of tibolone on the breast", *Eur. J. Obstet. Gynecol. Reprod. Biol.*, 80(2):235-8 (1998).

LUFKIN and ORY, "Relative value of transdermal and oral estrogen therapy in various clinical situations", *Mayo Clin. Proc.*, 69(2):131-5 (1994).

MOLINE, "Pharmacologic strategies for managing premenstrual syndrome", *Clin. Pharm.*, 12(3):181-96 (1993).

PLU-BUREAU, et al., "Percutaneous progesterone use and risk of breast cancer: results from a French cohort study of premenopausal women with benign breast disease", *Cancer Detect. Prev.*, 23(4):290-6 (1999).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

/ Patrea L. Pabst /

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Dated: March 11, 2009

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